

US EPA ARCHIVE DOCUMENT

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
HUMAN STUDIES REVIEW BOARD (HSRB)
PUBLIC TELECONFERENCE MEETING
Thursday, September 9, 2010
1:30 pm -3:00 pm (Eastern Time)***

**HSRB MEETING FOR REVIEW AND APPROVAL OF
DRAFT JUNE 23, 2010 HSRB MEETING REPORT**

**HSRB WEB SITE <http://www.epa.gov/osa/hsrb/>
Docket Telephone: (202) 566 1752
Docket Number: EPA-HQ-ORD-2010-0617**

**Meeting location via telephone only
Dial in number 866-299-3188; conference code 2025647189**

1:30 PM	Convene Meeting and Identification of Board Members – Jim Downing (Designated Federal Officer, HSRB, OSA, EPA)
1:40 PM	Meeting Administrative Procedures – Jim Downing, DFO
1:45 PM	Meeting Process –Sean Philpot, Ph.D. (HSRB Chair)
1:50 PM	Public Comments
2:00 PM	Board Discussion and Decision on Final Report – Sean Philpot, Ph.D. (HSRB Chair)

The Board's response to EPA charge questions presented at the June 23, 2010 meeting.

Completed Carroll-Loye Biological Research, Inc. Study LNX-002: Field Repellency of Two Picaridin-Based Personal Insect Repellents to Black Flies

Charge to the Board:

1. Is the CLBR study LNX-002 sufficiently sound, from a scientific perspective, to be used to estimate the duration of complete protection against black flies provided by the tested repellents?
2. Does available information support a determination that study LNX-002 was conducted in substantial compliance with subparts K and L 40 CFR Part 26?

Completed Carroll-Loye Biological Research, Inc. Study LNX-003: Laboratory Repellency of Two Picaridin-Based Personal Insect Repellents to Two Species of Ticks

Charge to the Board:

1. Is the CLBR study LNX-003 sufficiently sound, from a scientific perspective, to be used to estimate the duration of complete protection against ticks provided by the tested repellents?
2. Does available information support a determination that study LNX-003 was conducted in substantial compliance with subparts K and L 40 CFR Part 26?

Revised Product Performance Test Guidelines for Insect Repellents to be Applied to Human Skin

The Board recommended several changes or clarifications, including:

- Removal of the maximum-likelihood method requirement in the data analysis section;
- Clarification of recommendations regarding the use of positive controls, particularly with respect to the number of controls and the rationale for including them in the study;
- Careful consideration of recommendations regarding the recruitment and inclusion of so-called ‘vulnerable’ populations, including racial and ethnic minorities; and
- Encouraging the use of study designs that will enable investigators to collect data that will allow quantitative measurement of the repellent efficacy during the complete protection period.

2:55 PM **Summary and Next Steps** – Sean Philpot, Ph.D. (HSRB Chair) and Jim Downing (DFO)

3:00 PM **Adjournment**

* Please be advised that agenda times are approximate. For further information, please contact the Designated Federal Officer for this meeting, Jim Downing via telephone: (202) 564-2468 or email: downing.jim@epa.gov